REMARKS

Claims 27-20 and 43-52 are pending in this application.

On the first page of the Office Action, the Office maintained the rejection of claims 27-30 and new claims 43-52 under 35 U.S.C. § 112, second paragraph, asserting that the claims are indefinite because the first antibody could also be labeled and therefore, according to the Office, the antibodies of the boxed set might not be distinguished. Merely to further prosecution, Applicants have amended independent claims 27 and 43 to indicate that the first antibody, the capture antibody, is "unlabeled". This amendment is supported on page 10, lines 33-36, of the specification. Applicants respectfully request that the rejection be withdrawn.

On the second page of the Office Action, the Office required a new title of the invention. In the amendments to the specification, the title has been replaced with "Assay for the Diagnosis of Flaviviral Infection Using Antibodies with High Affinity for NS1 Protein of Flavivirus in Hexameric Form." Accordingly, Applicants respectfully request that any rejection or objection associated with the title be withdrawn.

On the second page of the Office Action, the Office raised a new rejection under 35 U.S.C. § 112, second paragraph, because it asserted that the phrase "comprising an assay" in claims 27-30 and 43-52 is indefinite. Merely to further prosecution, Applicants have amended independent claims 27 and 43 to recite "reagents" for the execution of an assay instead of "an assay". In light of this amendment, Applicants respectfully request that the rejection be withdrawn.

Finally, beginning on the third page of the Office Action, the Office rejected the claims and the specification under 35 U.S.C. § 112, first paragraph, for an asserted lack

of enablement and for failing to provide the best mode of carrying out the invention. Specifically, in the Office's interpretation, "[t]he claimed antibodies are biological materials necessary to practice the claimed invention as the starting material and the product claimed *per* se in the claims are necessary to practice the invention." Office Action at third page. Because, according to the Office, "[t]here is no evidence of record that the mouse hybridomas and monoclonal antibodies may be reproducibly produced without undue experimentation," *id.*, and "[e]xact replication of the cell line is an unpredictable event," *id.*, the Office required deposit of a hybridoma cell line.

Applicants traverse this rejection because under 37 C.F.R. § 1.802, "Biological material need not be deposited unless access to such material is necessary for the satisfaction of the statutory requirements for patentability under 35 U.S.C. 112." In contrast to the Office's interpretation of the claimed invention, it is not directed to a specific antibody, but, instead, encompasses any monoclonal or polyclonal antibody that has a high affinity for NS1 protein of a flavivirus in hexameric form. This is reinforced in the specification, which provides methods for preparing either monoclonal or polyclonal antibodies that can be used. *See* specification at pages 21-23 and 27-31.

In fact, the specification describes two different monoclonal antibodies, G18 and F22, which were "selected for their ability to bind, with high affinity, to different epitopes of the NS1 protein," specification at page 31, lines 29-31, thus demonstrating the reproducibility of the methods provided. Furthermore, the specification explains that "[t]he monoclonal antibodies selected not only reproduce the results obtained with the polyclonal approach, but they exhibit more marked reactivities than the polyclonal antibodies. The monoclonal tool developed therefore appears to be particularly suitable

for the diagnostic use which must be made of it." Specification at page 32, lines 1-6. Thus, the reproducibility of making the biological materials suitable for the claimed invention, as either monoclonal or polyclonal antibodies, is reinforced, and the best mode, monoclonal antibodies, is identified.

Because the invention as claimed and as described in the specification is directed to antibodies with the characteristic of having high affinity for the NS1 protein of the flavivirus in hexameric form, which can be produced by several reproducible methods, deposit of a hybridoma cell line should not be required to enable the claimed invention. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph, be withdrawn.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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